IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	CIVIL NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HON. ROBERT B. KUGLER

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

VOLUME I

- - -

June 4, 2021

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Videotaped remote deposition of SUSHIL JAISWAL, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 3:32 p.m., India Standard Time, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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learning that this company that's telling you there's no genotoxic impurities in your drug also has no idea about degradation and stuff, you guys still weren't testing the API, right?

MS. BRANCATO: Objection to form.

THE WITNESS: I think I have already clarified. The genotoxic impurity, the process impurity, is based upon the chemistry. And the degradation product result is a different aspect.

The degradation product is always being monitored through the testing method. And for the genotoxic impurity, if it is there, it has to be -- for that, method is to be there in place.

But this genotoxic alerts is always being -- like, throughout the DMF process, vendor has already given a claim that it is meeting the ICH M7 requirement.

BY MS. PENDLEY:

Q. Okay. But despite learning that your inspector had concerns about your API manufacturer, you still did not confirm the testing they were giving you about genotoxic impurities; is that right?

MS. BRANCATO: Objection to form.

THE WITNESS: No, I think -- I think I'm not fully in agreement, because those are the findings what you have seen in 2015 report, the citation, those are not relating to the genotoxic part, they are relating to the degradation impurities. And genotoxic impurity is not a degradation impurity.

BY MS. PENDLEY:

Q. Okay. Right. But Jenny Yang told you guys that she has concerns about ZHP, says they're not concerned with patient safety, and they have no

indicated, as a part of, like, our own program, every batch was tested. I'm talking about the API batches being tested by us.

And we do maintain the printout for all impurities which is being part of specification.

And we never seen adverse trend on those impurity levels. And that is the reason to believe that those degradation which is being cited as an observation was not -- that was a concern, but that was not the real concern.

BY MR. NIGH:

Q. Yeah, but when you're looking for impurities, you're not -- you didn't do your own residual solvent chromatography on any of these drugs, correct? You didn't do that testing?

A. See, we always do -- we are talking about the impurities. And we are always -- say we are talking about degradation product, what she has cited